

### **REMARKS**

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested.

#### **Status of the claims**

Claims 3-5 and 11-24 are pending in the application. Claims 3-5, 11-14, 16, 18 and 20-21 are amended. Claims 3-5, 11 and 21 are amended to obviate the new matter rejection, as discussed below. Claims 3-5 and 11 are amended to remove esters of pentaerythritol oligomers as specific components of the ester mixtures. Support for claim 21 to include the limitation of "predominantly unbranched" with regard to the fatty acid is found, *inter alia*, on page 3, lines 22-26 of the substitute specification as originally filed. Additional claim amendments have been made for clarity. Support is found throughout the substitute specification as originally filed. No claims are cancelled. New claims 22-24 are hereby added. Support is found throughout the substitute specification as originally filed.

No new matter has been added.

#### **Summary of the invention as Claimed**

As currently amended, one aspect of the claimed invention is drawn to a fatty acid ester mixture of pentaerythritol, wherein the fatty acid is a C6-C22 fatty acid or fatty acid mixture, or a mixture of C16 and C18 fatty acids, and wherein the ester mixture contains less than 0.3% by weight of esters containing C17 fatty acid acyl groups, and has a melting point of at least 30°C (claims 3-5 and 21-24). The fatty acid ester mixture contains monoesters, diesters and triesters (claim 4), and may also contain tetraesters (claim 5). In one embodiment of the invention as now claimed, the fatty acid esters are predominantly unbranched (claims 21, 24).

Another embodiment of the invention as now claimed is drawn to a cosmetic and/or pharmaceutical composition comprising the above fatty acid ester mixture (claims 11-20).

**Rejections under 35 U.S.C. § 112, first paragraph**

Previously pending claims 3-5 and 11-21 were rejected under 35 U.S.C. § 112, first paragraph, as containing new matter. The phrase C17 "fatty acid-containing component" found in claims 3-5, 11 and 21, was found by the Examiner to not be supported in the application as originally filed, and broadened the claim to include fatty acids and components other than fatty acids. Although the undersigned does not agree with the Examiner on this point, in order to further prosecution the claims have been amended to recite "esters containing C17 fatty acid acyl groups". In view of this amendment the Examiner is requested to withdraw the new matter rejection.

**Rejections under 35 U.S.C. § 103(a)**

Claim 3, as previously presented, was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lindner (US 4,332,702) in view of Memita, et al. (WO 2002/22548, using US 6,939,980 as English translation; "Memita"), further in view of Miranol Chemical Co. (EP 0163806; "Miranol 1"). Applicants respectfully traverse the rejection.

Lindner discloses partial esters of pentaerythritol as internal lubricating agents for lowering the viscosity of polyvinyl chloride resins, as well as hydrogen chloride scavengers. The fatty acid portion of the partial pentaerythritol esters comprises 0-10% C14, 0-5% C15, 30-60% C16, 0-5% C17, and 30-60% C18. The partial esters are 25-45% monoester, 40-60% diester, and 15-30% triester, being **substantially free of the tetraester**.

The Examiner acknowledged that Lindner's esters do not have applicants' claimed melting point of at least 30°C. Memita was joined to overcome this deficiency.

Memita discloses a process for producing an ester comprising reacting an alcohol or polyol with a C5-C30 carboxylic acid to obtain a crude esterified product, adding 5-100 parts of a hydrocarbon solvent per 100 parts of crude ester, and neutralizing with an aqueous alkali solution. The polyols include pentaerythritol.

However, the described esters are fully esterified **tetraesters** as disclosed in Memita's Examples. The pentaerythritol esters disclosed in Examples 1, 2, and 24-26, as well as their corresponding comparative examples, are all prepared with a reaction

stoichiometry of >4:1 acid:pentaerythritol, and the product esters are all characterized by low hydroxyl values, which demonstrates that the free OH content of the products is low (ie. the product esters must be **tetraesters**). Thus, the products of Examples 1 and 2 have hydroxyl values of 0.8 mg KOH/g and 1.5 mg KOH/g, respectively. Specifically, the compounds of Example 2 and Comparative Example 2, cited by the Examiner, were prepared with a 4.125:1 ratio of (total stearic plus palmitic) acid:pentaerythritol, and both products have hydroxyl values of 1.5 mg KOH/g. As such, the compounds cited by the Examiner, of mp 67.7°C and 63.4°C are **tetraesters**. Nowhere in Memita is there disclosure of partial esters of pentaerythritol.

This is in contrast to Lindner's esters, which are partial esters "**substantially free of tetraester**" (Lindner, col 2, lines 25 and 49; Example 1, column 5, lines 58-59; claims 1 and 5). Since the esters of Linder and Memita are mutually exclusive structurally, their melting points cannot be related, and Memita cannot be joined to Lindner to supply the melting point deficiency.

Further Lindner's utility is not in the cosmetic arts, instead being drawn to use as internal lubricants and HCl scavengers in polyvinyl chloride compositions. Therefore, the disclosed utility of Lindner would not teach, motivate or suggest to one skilled in the art that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions.

The Examiner joined Miranol 1 to overcome the deficiency in Lindner with regard to pentaerythritol **oligomers**. Miranol 1 discloses a mixture of partially esterified pentaerythritol oligomers with C6-18 fatty acids, useful as moisturizers and emollients in cosmetics. There is no teaching or indication in Miranol regarding the relative ratios of C16, C17 and C18, which is key to applicants' invention. Note that the preferred fatty acid carbon range of Miranol 1 is 12-16 (page 5, lines 7-11), thereby lacking the C18-component.

However, since applicants have elected to remove pentaerythritol oligomers from the claims, the cited art is moot, and the claim as presently amended is patentably unobvious over the cited art.

Claim 4, as previously presented, was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lindner in view of Memita, further in view of Miranol 1. Applicants respectfully traverse the rejection.

Lindner and Memita are discussed above. Again, the difference between applicants' ester and that of Lindner is acknowledged by the Examiner to be applicants' presently claimed melting point. The Examiner joined Memita to cure this deficiency.

Again, the esters of Lindner are required to be "substantially free of the tetraester", in contrast to Memita's tetraesters. As such, the esters of Lindner and Memita are mutually exclusive structurally, and their melting points cannot be related. Therefore Memita cannot be joined to Lindner to supply the melting point deficiency.

Further Lindner's utility is not in the cosmetic arts, instead being drawn to use as internal lubricants and HCl scavengers in polyvinyl chloride compositions. Therefore, the disclosed utility of Lindner would not teach, motivate or suggest to one skilled in the art that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions.

Again, the Examiner joined Miranol 1 to overcome the deficiency in Lindner with regard to pentaerythritol oligomers. However, since applicants have elected to remove pentaerythritol oligomers from the claims, the cited art is moot.

Therefore the claim as presently amended is patentably unobvious over the cited art.

Claim 5, as previously presented, was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sakurai et al. (US 4,113,635, "Sakurai"). Applicants respectfully traverse the rejection.

Sakurai discloses rust-proof lubricant compositions for coating metals, comprising mono-, di- and tri- partial esters of pentaerythritol and fatty acids having more than 6 carbon atoms. Melting points are stated to be in the range of 30-60°C. Example 3 discloses a fatty acid pentaerythritol ester mixture that is 20% monoester, 30% diester, 40% triester, and 10% tetraester, whereas applicants' claim 5 discloses about 12-19% monoester, about 25-35% diester, about 30-40% triester, and about 6-11% tetraester.

The Examiner stated that "[a]ccording to the results in Table 3 the lubricant of Example 3 exhibited satisfactory results for Applicants' intended purpose" (Office Action, page 15, number 20). Applicants do not agree with the Examiner's statement. It is noted that Sakurai's utility is not in the cosmetic arts, instead being drawn to use as rust-proof lubricant compositions for coating metals. Table 3 lists the activities of "degreasing ability", "rust preventiveness", "oil stain", and "press lubricity", none of which are related to the cosmetic or pharmaceutical arts. Therefore Sakurai does not teach, motivate or suggest to one skilled in the cosmetic/pharmaceutical arts that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions. Further, we note that the composition of Example 6, which contains a fatty acid pentaerythritol mixture close to applicants' claim 4 ester mixture (the monoester content of 30% is outside applicants' claimed range of 10-25%) is **not satisfactory** as a rust-proof lubricant, as recorded in Table 3. Thus there would appear to be no correlation of Sakurai's rust-proof lubricant properties with applicants' cosmetic/pharmaceutical properties.

Therefore the claim as presently amended is patentably unobvious over the cited art.

Claims 11-20, as previously presented, were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barth et al. (US 2,441,555; "Barth") and Burrell et al. (US 2,427,255; "Burrell"), in view of Miranol 1, Plough, Inc. (EP 0179416; "Plough"), Miranol Chemical Co. (EP 0151992; "Miranol 2"), Bauer et al. (WO 2003/028690; using US 2004/0258721 as English translation; "Bauer") and Sakurai. Applicants respectfully traverse the rejection.

Barth discloses a process for preparing mixed esters of pentaerythritol with fatty acids containing 10 or more carbon atoms. These partial esters are further reacted with a different acid or anhydride (eg. acetic anhydride) to form the fully esterified tetraesters. These product tetraesters are listed in Table I, together with their physical properties and starting materials. The melting point of 36-38°C quoted by the Examiner is for the **tetraester** pentaerythritol triacetate monostearate, not the starting hydroxy ester (Table 1, first entry). With respect, the Examiner's statement that "...in Table 1 all of the ester products are shown to have melting points between 36 and 38°C" is an

overgeneralization, since only one compound has that melting range, with the others being waxes or oils. Further, the physical data are for the **tetraester** products and are therefore unrelated to applicants partial ester mixtures.

Further, the esters of Barth are reported to be useful in the plastics and coatings arts as modifiers, which are unrelated to cosmetic and/or pharmaceutical utility. Thus, the disclosed utility of Barth would not teach, motivate or suggest to one skilled in the art that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions.

Burrell discloses a process for the production of synthetic waxes comprising at least partial esters of pentaerythritol/pentaerythritol oligomers and fatty acids with a carbon content of C10-C22 or more. It is noted that all Examples use **technical** pentaerythritol ("Pentek", which is a mixture of 85% pentaerythritol and 15% dipentaerythritol; column 5, lines 51-55), containing dipentaerythritol, therefore the melting points of the disclosed esters are unrelated to applicants ester mixtures of only monomeric pentaerythritol, as currently amended.

Further, the esters of Burrell are disclosed to be applicable for 17 different uses (column 9, line 60 through column 10, line 8), ranging from non-drip candle coatings to plastic compositions, all of which are unrelated to cosmetic and/or pharmaceutical utility. The "lubricant" utility specifically pointed out by the Examiner is Burrell's utility number 5, "mold lubricant for stamping operations or plastic molding", which is clearly unrelated to cosmetic and/or pharmaceutical utility. Therefore, the disclosed utility of Burrell would not teach, motivate or suggest to one skilled in the art that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions.

As correctly noted by the Examiner, Barth and Burrell do not indicate cosmetic or pharmaceutical utility; that the cosmetic or pharmaceutical composition may comprise a wax component, nonionic surfactant and an oil component; or contain mono-, di- and tri-esters in the mixture. In order to overcome these deficiencies in Burrell and Barth the Examiner joined Miranol 1, Miranol 2, Plough and Bauer.

As discussed above, Miranol 1 is drawn to esters of pentaerythritol **oligomers**, whereas applicants' claims as presently amended are drawn only to (monomeric)

pentaerythritol. Likewise, Miranol 2 is drawn to esters of tripentaerythritol (a pentaerythritol oligomer). Therefore Miranol 1 and Miranol 2 are unrelated to applicants' presently amended claims, and cannot cure the deficiencies disclosed above.

Plough and Bauer both are drawn to fully esterified tetraesters, and are therefore unrelated to applicants' partial ester mixtures as presently amended. The Examples 93, 94 and 96 of Bauer (p. 46) specifically pointed out by the Examiner, disclose pentaerythritol **tetra**isostearate. Also, Plough discloses "pentaerythritol **tetra** (C20 – C24) aliphatic hydrocarbon carboxylates" (page 2, bottom paragraph). In contrast, applicants' claims are drawn to fatty acid partial ester mixtures, with specific ranges of mono-, di-, tri-, and tetra-esters. Therefore Plough and Bauer are unrelated to applicants' presently amended claims, and cannot cure the deficiencies disclosed above.

Further, even if the pentaerythritol tetraesters of Plough were relevant art, which they are not as discussed above, applicants submit herewith a declaration disclosing comparative testing of a composition of the invention versus a composition comprising the preferred tetraester of Plough, pentaerythritol tetrabeheate (page 3, top paragraph; all Examples). As clearly shown by the comparative data in the declaration submitted herewith, the ester mixture of the invention provides a useful and stable cosmetic emulsion, whereas the comparison tetraester of Plough does not (emulsion separated). Thus the ester mixtures and compositions of applicants are distinguished over the prior art, and are patentably unobvious.

The Examiner also joined Sakurai, which discloses a mixture of pentaerythritol partial esters useful as rust-proof lubricants, not cosmetics. Sakurai is unrelated to the cosmetic arts, but rather discloses compounds of use as rust-proof lubricant compositions for coating metals. Sakurai is further discussed below in relation to the anticipation rejection.

Thus, taken *in toto*, the combination of Barth, Burrell, Miranol 1, Miranol 2, Plough, Bauer and Sakurai is insufficient to lead one skilled in the art at the time of the invention, to applicants' invention, without the benefit of applicants' present disclosure. This would be impermissible hindsight reconstruction. Applicants' claims as presently amended define patentably unobvious matter.

**Rejections under 35 U.S.C. § 102(b)**

Claim 21 as previously presented was rejected under 35 U.S.C. § 102(b) as being anticipated by Sakurai. Applicants respectfully traverse the rejection.

Sakurai is as discussed above.

First, it is noted that each and every limitation of the claim must be recited in the cited art in order for a claim to be anticipated. As presently amended claim 21 recites that the C6-C22 fatty acid is **predominantly unbranched**. There is no such limitation in Sakurai; there are no limitations indicating "linear" (unbranched) or "branched", "saturated" or "unsaturated", as is commonly found in, and important to, the cosmetic and pharmaceutical arts. Also, there is no particular carbon limitation for the fatty acids disclosed in Sakurai, although specific examples of suitable fatty acids are provided. Indeed the fatty acid disclosure of Sakurai is so broad as to teach that this feature is not particularly important, which would be reasonable for an industrial lubricant.

Second, it is noted that Sakurai is also missing applicants' negative limitation for the C17-containing ester component.

In conclusion, each and every limitation of applicants' claim 21 as presently amended is not taught by the cited reference. Therefore applicants' claim as presently amended is novel and patently unobvious over Sakurai.



**Conclusion**

In summary, in view of the above claim amendments and remarks, and the Declaration of Helga Gondek under 37 C.F.R. 1.132, applicants believe that the pending claims as amended are in condition for allowance. The Examiner is respectfully requested to reconsider, withdraw the rejections and allow the claims.

If any additional fees are required in support of this application, authorization is granted to charge our Deposit Account No. 50-1943.

Respectfully submitted,

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